510 (K) SUMMARY

MAY 0 6 2014

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification:**

Shandong Yifan Plastic Products Co., Ltd.
Building 11, Sunny Industries Park,
Shuangyang Village, Zichuan District,
Zibo City, Shandong, China 255000
Date summary prepared: April 15, 2014

2. **Name of the Device:**

Shandong Yifan Plastic Products Co., Ltd.
Powder-free Vinyl Patient Examination Gloves, Yellow Color

3. **Common name/classification name of the Device:**

Regulation Number: 21 CFR 880.6250,
Regulation Name: Patient Examination Glove
Regulation Class: Class I
Product Code: LYZ

4. **Contact Person:**

Jennifer Guo, Tel: 909-548-4828

5. **Predicate Device Information:**

Shijiazhuang Hongxiang Plastic Products Ltd.
Synthetic Vinyl Patient Examination Gloves – Powder Free (K992821)

6. **Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, and meets all requirement of ASTM Standard D5250-06. The subject device is a garment covering the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb. And vinyl films form a barrier to body fluid and blood-borne pathogens, and that the vinyl rubber is water tight under normal conditions of use. Its tensile

properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

7. **Intended Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

8. **Comparison to Predicate Devices:**

Shandong Yifan Plastic Products Co., Ltd. Powder-free Vinyl Patient Examination Gloves, Yellow Color are substantially equivalent in safety and effectiveness to the Shijiazhuang Hongxiang Plastic Products Co., Ltd.(K992821)

Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device	Predicate Device (K992821)
Description	Shandong Yifan Plastic Products Co., Ltd Powder-Free Vinyl Patient Examination Gloves, Yellow Color	Shijiazhuang Hongxiang Powder-free Vinyl Patient Examination Gloves
Indication for Use	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.
Labeling: Instruction for use	A garment covering the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb.	Substantially equivalent
Labeling: Labels on the carton	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.	Substantially equivalent
Device Materials	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)	Substantially equivalent
Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 16.9 Average Ultimate Elongations: 550%	Substantially equivalent
After Aging: Tensile	Average Tensile Strength (Mpa):	Substantially equivalent

Strength(Mpa) and Ultimate Elongations	14.4 Average Ultimate Elongations: 500%	
Overall Length on Medium Size	Average over 230mm	Substantially equivalent
Width of Palm on Medium Size	Average 95mm	Substantially equivalent
Palm Thickness	Average 0.085 mm	Substantially equivalent
Figure Thickness	Average 0.090 mm	Substantially equivalent
Residual Powder	Residual powder content ≤ 2 mg per glove per ASTM D6124-06.	Substantially equivalent
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	Substantially equivalent
Biocompatibility Result: Primary Skin Irritation	Not a irritant	Substantially equivalent
Dermal Sensitization	Not a sensitizer	Substantially equivalent
Summary of comparison	Shandong Yifan Plastic Products Co., Ltd Powder-Free Vinyl Patient Examination Gloves, Non-Sterile, Yellow Color (subject device) and Shijiazhuang Hongxiang Powder-free Vinyl Patient Examination Gloves (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.	

9. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Shandong Yifan Plastic Products Co., Ltd. glove production are based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level I, meeting these requirements, Primary Skin irritation and Skin Sensitization testing was conducted with results showing no primary skin irritant or sensitization reactions.

The subject gloves are powder free.

10. Discussion of Clinical Tests Performed:

Not Applicable

11. Conclusions:

The subject device, Shandong Yifan Plastic Products Co., Ltd. Powder-Free Vinyl Patient Examination Gloves, Yellow Color, Non-Sterile, is substantially equivalent to the predicate device (K992821) Shijiazhuang Hongxiang Powder-free Vinyl Patient Examination Gloves, in intended use as well as technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 6, 2014

Shandong Yifan Plastic Products Company Limited
C/O Ms. Ling Zhu
Official Correspondent
12390 East End Avenue
Chino, CA 91710

Re: K122656
Trade/Device Name: Powder-Free Vinyl Patient Examination Gloves, Yellow Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: April 23, 2014
Received: April 25, 2014

Dear Ms. Zhu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

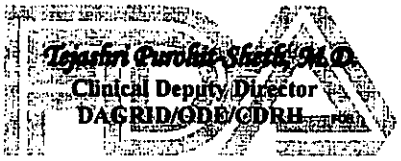
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K122656

Device Name
Powder-free Vinyl Patient Examination Gloves, Yellow Color

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000558B4, cn=Elizabeth F. Claverie -S
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